

FINAL REPORT

CLASS V TOXICITY TEST IN MICE  
AND RABBITS ADMINISTERED TEST ARTICLE  
ELASTOMER SHELL

Summary/Conclusion

A USP Toxicity Test was performed by systemic and intracutaneous injections of sodium chloride, EtOH, sesame seed oil, and PEG extracts of test article Elastomer Shell in Albino Swiss Webster Mice and New Zealand Albino Rabbits.

In conclusion, no signs of toxicity were noted systemically or intracutaneously for the sodium chloride, EtOH, sesame seed oil, or PEG extracts; therefore, under the conditions of this test, Elastomer Shell is considered to be non-toxic.

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CLASS V TOXICITY TEST IN MICE  
AND RABBITS ADMINISTERED TEST ARTICLE  
GEL [REDACTED]

Summary/Conclusion

A USP Toxicity Test was performed by systemic and intracutaneous injections of sodium chloride, EtOH, sesame seed oil, and PEG extracts of test article Gel [REDACTED] in Albino Swiss Webster Mice and New Zealand Albino Rabbits.

In conclusion, no signs of toxicity were noted systemically or intracutaneously for the sodium chloride, EtOH, sesame seed oil, or PEG extracts; therefore, under the conditions of this test, Gel [REDACTED] is considered to be non-toxic.

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CLASS V TOXICITY TEST IN MICE  
AND RABBITS ADMINISTERED TEST ARTICLE  
LEAF VALVE ASSEMBLY

Summary/Conclusion

A USP Toxicity Test was performed by systemic and intracutaneous injections of sodium chloride, EtOH, sesame seed oil, and PEG extracts of test article Leaf Valve Assembly in Albino Swiss Webster Mice and New Zealand Albino Rabbits.

In conclusion, no signs of toxicity were noted systemically or intracutaneously for the sodium chloride, EtOH, sesame seed oil, or PEG extracts; therefore, under the conditions of this test, Leaf Valve Assembly is considered to be non-toxic.